

MODEL STANDING ORDERS

Varicella Vaccine
Live Virus Vaccine

Note: These model standing orders are current as of April 2004. All standing orders should be reviewed carefully against the most current recommendations and may be revised by the clinician signing them.

Varicella vaccine is **recommended** for individuals ≥ 12 months of age in the following groups:

- all children 12 - 18 months of age, without a reliable history of varicella. A reliable history of chickenpox consists of: good parental history, physician diagnosis, or serologic proof of immunity;
- susceptible children by the 13th birthday (due to increased complications after this age);
- susceptible adolescents by the 19th birthday;
- susceptible persons ≥ 12 months of age who will have household contact with persons at high risk of serious complications from varicella (e.g., immunocompromised persons);
- susceptible health care workers;
- susceptible non-pregnant women of childbearing age;
- persons who live or work in settings with a high likelihood of transmission of varicella zoster virus (VZV) (e.g., teachers of young children, day care workers, and residents and staff in institutional settings);
- persons who live or work in settings in which VZV transmission can occur (e.g., college students, inmates and staff at correctional facilities, and military personnel);
- susceptible adolescents and adults living in households with children;
- susceptible international travelers; and
- susceptible contacts of confirmed or suspected cases of varicella.¹

¹ Varicella vaccine given ≤ 3 days (and possibly up to 5 days) after exposure may prevent or modify varicella disease.

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ORDER:

1. Provide patient, or patient's parent or guardian, with a copy of the Vaccine Information Statement (VIS) and answer any questions.
2. Screen for contraindications (Table 1).
For women of reproductive age (12-50 years of age):
 - document pregnancy status;
 - explain the theoretical risks to those not pregnant and advise her not to get pregnant for ≥ 1 month;
 - it is sufficient to ask a woman if she is pregnant; a pregnancy test is **not** necessary;
 - optional, additional documentation may include date of last menstrual period and/or method of birth control, if any.
3. Administer varicella vaccine 0.5 ml subcutaneously (SC) in the anterolateral aspect of the thigh or the upper outer triceps area by injecting the needle at a 45° angle in a pinched-up fold of skin and SC tissue. Use a 5/8- to 3/4-inch, 23- to 25-gauge needle. Follow the recommended schedule (see Table 2).
Always check the package insert prior to the administration of any vaccine.
4. Give varicella vaccine simultaneously with all other live or killed immunizations according to the recommended schedule and patient's current vaccine status. (For additional information on simultaneous administration of varicella vaccine, please refer to Table 2.)
5. If possible, observe patient for an allergic reaction for 15 - 20 minutes after administering vaccine.
6. Facilities and personnel should be available for treating immediate hypersensitivity reactions.
7. Report clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967, or via the VAERS website: www.vaers.org.
8. See the MIP document *General Protocols for Standing Orders* for further recommendations and requirements regarding vaccine administration, documentation and consent.

Varicella Vaccine Storage and Handling
<ul style="list-style-type: none">• Varicella vaccine must be stored in a freezer with a temperature of -15° C (+5° F) or colder.• Once reconstituted, the vaccine must be used immediately. If the vaccine is not used within 30 minutes, it must be discarded.• If varicella vaccine is stored at refrigerator temperature (2-8°C or 36-46°F) prior to reconstitution, it must be used within 72 hours of refrigeration. Varicella vaccine stored at refrigerator temperature which is not used within 72 hours must be discarded.

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Table 1. Contraindications and Precautions to Varicella Vaccine

Valid Contraindications and Precautions to Varicella Vaccine	Invalid Contraindications (Varicella Vaccine should be given)
Anaphylactic reactions to a previous dose of varicella vaccine, gelatin, neomycin, or to any other component of the vaccine (see package insert for specific components)	Mild illness with or without low-grade fever
	Non-anaphylactic reaction to any component of the vaccine
Immunodeficiency in the recipient, including: congenital immunodeficiency; blood dyscrasias; leukemia; lymphoma; other malignancies; cellular immune deficiencies (including HIV infection <u>with</u> immunosuppression) ¹ ; and long-term immunosuppressive therapy ²	Persons with impaired humoral immunity (eg., hypgammaglobulinemia, dysglobulinemia, agammaglobulinemia)
	HIV-infected children in CDC Class N1 or A1 with age-specific CD4+ T-lymphocyte percentages of $\geq 25\%$
High-dose steroid therapy daily or on alternate days for ≥ 14 days (≥ 2 mg/kg/day or ≥ 20 mg/day of prednisone) ³ (For additional information on steroids, see Table 3.)	Asymptomatic or mildly symptomatic HIV infection
	Children with acute lymphoblastic leukemia (ALL) in remission for ≥ 12 consecutive months and conforming to certain other criteria ¹
Long-term salicylate therapy ⁴	<ul style="list-style-type: none"> Low-dose or moderate-dose steroid therapy daily or on alternate days for < 14 days (< 2 mg/kg /day or < 20 mg/day prednisone) Physiologic maintenance doses of steroids (For additional information on steroids, see Table 3.)
Antiviral drugs active against herpesviruses (e.g., acyclovir or valacyclovir) ≤ 24 hrs before vaccination ⁵	
Active untreated tuberculosis ⁶	
Pregnancy ⁷ (It is sufficient to ask a woman if she is pregnant; a pregnancy test is not necessary.)	Simultaneous TB skin testing ⁸
Precautions to Varicella Vaccine : <ul style="list-style-type: none"> Moderate or severe illness with or without fever (temporary precaution) Recent (≤ 11 months) administration of an immunoglobulin (IG)-containing blood product (see Table 4 for suggested intervals between varicella and IG-containing preparations) Family history of immunodeficiency⁹ High-dose systemic steroids daily or on alternate days for < 14 days (< 2 mg/kg/day or < 20 mg/day prednisone)¹⁰ Topical, aerosol, or local injection steroids¹¹ (For additional information steroids, see Table 3.) 	TB or positive PPD (on treatment) ⁶
	Immunodeficient family member ⁹ or household contact
	Pregnancy in recipient's mother or other close or household contact
	Breast-feeding
	Anaphylactic reaction to eggs

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Footnotes for Table 1. Contraindications and Precautions to Varicella Vaccine

- ¹ Varicella vaccine should **not** be administered to persons who have cellular immune deficiencies, but persons with impaired humoral immunity may be vaccinated. Varicella vaccine should be considered for asymptomatic and mildly symptomatic HIV-infected children in CDC Class N1 or A1 with age-specific CD4+ T-lymphocyte percentages of $\geq 25\%$. An investigational protocol exists for use of varicella vaccine in patients with acute lymphoblastic leukemia (ALL) in remission. Information is available by calling Bio-Pharm Clinical Services at (215) 283-0897.
- ² After the cessation of chemotherapy and other immunosuppressive therapy, varicella vaccine should be deferred for ≥ 3 months, with the exception of corticosteroid therapy. (See footnotes No. 3, 9 and 10 below. For additional information on steroids see Table 3.)
- ³ For patients on high dose, long-term steroids, varicella vaccine should be deferred for ≥ 1 month post-treatment. (See Table 3.)
- ⁴ Salicylate therapy should not be administered for ≥ 6 weeks after varicella vaccine has been given.
- ⁵ Antiviral drugs active against herpesviruses (e.g. acyclovir or valacyclovir) might reduce the efficacy of live attenuate varicella vaccine. These drugs should be discontinued ≥ 24 hours before the administration of varicella vaccine, if possible.
- ⁶ A theoretical basis exists for concern that varicella vaccine (like measles vaccine) might exacerbate tuberculosis. Consequently, before administering varicella to persons with untreated active tuberculosis, initiating antituberculosis therapy is advisable.
- ⁷ Non-pregnant women should avoid pregnancy for ≥ 4 weeks post vaccination. Merck & Co. and CDC have established a registry to assess the outcomes of pregnancies when vaccination with varicella vaccine occurred within three months of pregnancy or anytime during pregnancy. To report exposures to varicella vaccine during pregnancy, call (800) 986-8999.
- ⁸ Although no data is available, it is possible that varicella vaccination (like measles vaccination) may temporarily suppress tuberculin reactivity. If TB testing cannot be done on the day of varicella vaccination, it should be postponed for ≥ 4 weeks.
- ⁹ The benefits of giving varicella vaccine to the household contacts of an immunosuppressed individual outweigh any potential risks. However, if an individual has a family history of congenital or hereditary immunodeficiency in parents or siblings, varicella vaccine should not be administered to that individual unless their own immune competence has been clinically substantiated or verified by a laboratory.
- ¹⁰ Patients receiving high dose, short-term steroids can receive live virus vaccines immediately after discontinuation of treatment. However, some experts advise waiting until ≥ 2 weeks after cessation of therapy, if possible (e.g., if the patient's condition allows temporary cessation). (See Table 3.)
- ¹¹ Varicella vaccine can be given to patients receiving steroids by topical, aerosol, or local injection. However, if therapy is prolonged and there is any clinical or laboratory evidence of immunosuppression, varicella vaccine should be deferred for ≥ 1 month post treatment. (See Table 3.)

Table 2. Recommended Varicella Vaccine Schedule

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Group	Number of Doses
Children 12 months - 12 years of age	1 dose given at 12 – 18 months of age (assess and administer to susceptibles at entry into day care, kindergarten and 7 th grade)
Adolescents and adults ≥ 13 years of age	2 doses, given 4 - 8 weeks apart
HIV-infected children ≥ 12 months of age in CDC Class N1 or A1 with age-specific CD4+ T-lymphocyte percentages of $\geq 25\%$	2 doses , given 3 months apart
Notes on varicella vaccine: <ul style="list-style-type: none"> Timing of administration of varicella vaccine and other live vaccines: <ol style="list-style-type: none"> 1) Varicella and MMR vaccines not administered on the same day should be given ≥ 4 weeks apart. 2) Varicella and smallpox vaccines may not be administered on the same day and must be separated by ≥ 4 weeks. 3) Live oral vaccines (Ty21a typhoid vaccine, oral polio vaccine) and varicella vaccine can be given at any time before, with, or after each other. Varicella vaccine and immune globulin (IG)-containing blood products: IG-containing blood products can diminish the antibody response to varicella vaccine: <ul style="list-style-type: none"> Simultaneous administration: Do not give immune globulin (IG)-containing blood products and varicella vaccine simultaneously. If unavoidable, give at different sites and revaccinate or test for seroconversion at the recommended interval. The duration of interference of IG-containing blood products and varicella vaccine is dose-related and can range from 3 – 11 months. See Table 4. If varicella vaccine is given first: Defer IG for ≥ 2 weeks. If IG is given first: The interval between IG and varicella vaccine depends on the product, dose, and indication (see Table 4). Antiviral drugs active against herpesviruses (e.g., acyclovir or valacyclovir) might reduce the efficacy of varicella vaccine. These drugs should be discontinued ≥ 24 hours before administration of varicella vaccine, if possible. 	

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Table 3. Guidelines for Administration of Live Virus Vaccines and Steroid Therapy *

Steroid Therapy	Recommendations for Deferral
High dose systemic steroids daily or on alternate days for ≥ 14 days (≥ 2 mg/kg QD or ≥ 20 mg QD if weight >10 kg of prednisone)	Defer live virus vaccines for ≥ 1 month after treatment has stopped.
High dose systemic steroids daily or on alternate days for < 14 days (≥ 2 mg/kg QD or ≥ 20 mg QD if weight >10 kg prednisone)	Can give live virus vaccines immediately after treatment is discontinued. However, some experts recommend deferring until ≥ 2 weeks after treatment has stopped, if possible.
Low or moderate doses of systemic steroids given daily or on alternate days (< 2 mg/kg QD or < 20 mg QD if weight >10 kg of prednisone)	Can give live virus vaccines on treatment.
Physiologic maintenance doses of steroid (replacement therapy)	Can give live virus vaccines on treatment.
Topical, aerosol or local injections of steroids (e.g., skin, aerosol, eyes, intra-articular, bursal, tendon injections)	Can give live virus vaccines on treatment. However, if this therapy is prolonged and there is any clinical or laboratory evidence of immunosuppression, defer for ≥ 1 month after treatment has stopped.
Individuals with a disease which in itself is considered to suppress the immune response and who are receiving systemic or locally acting steroids	Should not give live virus vaccines, except in special circumstances.

* Steroid therapy is **not** a contraindication for administration of **killed** vaccines.

Adapted from : American Academy of Pediatrics. Immunization in Special Clinical Circumstances. In: Pickering LK, ed. *Red Book: 2003 Report of the Committee on Infectious Diseases*. 26th ed. p. 74-75.

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Table 4. Suggested Intervals between Administration of Immunoglobulin Preparations and Measles-Containing and Varicella Vaccines

Product/Indication	Dose, including mg immunoglobulin G (IgG)/kg body weight¹	Recommended interval before measles or varicella vaccination (months)
Respiratory syncytial virus immune globulin (IG) monoclonal antibody (Synagis™)	15 mg/kg intramuscularly (IM)	None
Tetanus IG	250 units (10 mg IgG/kg) IM	3
Hepatitis A IG		
Contact prophylaxis or international travel < 3 mos	0.02 mL/kg (3.3 mg IgG/kg) IM	3
International travel 3 – 5 mos	0.06 mL/kg (10 mg IgG/kg) IM	3
Hepatitis B IG	0.06 mL/kg (10 mg IgG/kg) IM	3
Rabies IG	20 IU/kg (22 mg IgG/kg) IM	4
Varicella IG	125 units/10 kg (20-40 mg IgG/kg) IM, maximum 625 units	5
Measles prophylaxis IG		
Standard (i.e., nonimmunocompromised) contact	0.25 mL/kg (40 mg IgG/kg) IM	5
Immunocompromised contact	0.50 mL/kg (80 mg IgG/kg) IM	6
Blood transfusion		
Red blood cells (RBCs), washed	10 mL/kg negligible IgG/kg intravenously (IV)	None
RBCs, adenine-saline added	10 mL/kg (10 mg IgG/kg) IV	3
Packed RBCs (hematocrit 65%)	10 mL/kg (60 mg IgG/kg) IV	6
Whole blood (hematocrit 35%-50%)	10 mL/kg (80-100 mg IgG/kg) IV	6
Plasma/platelet products	10 mL/kg (160 mg IgG/kg) IV	7
Cytomegalovirus intravenous immune globulin (IGIV)	150 mg/kg maximum IV	6
Respiratory syncytial virus prophylaxis IGIV	750 mg/kg IV	9
IGIV		
Replacement therapy for immune deficiencies	300-400 mg/kg IV	8
Immune thrombocytopenic purpura	400 mg/kg IV	8
Immune thrombocytopenic purpura	1,000 mg/kg IV	10
Kawasaki disease	2 grams/kg IV	11

Note on other live vaccines: Blood and other antibody-containing products (except washed red blood cells) can also diminish the response to rubella vaccine, and potentially to mumps vaccine. Therefore, after immune globulin preparations or other antibody-containing products are received, mumps and rubella vaccines should be deferred for ≥ 3 months. If RSV-IGIV is given, mumps, rubella and varicella vaccines should be deferred for ≥ 9 months. If RSV-IM is given, no deferral is needed for any live virus vaccines.

Adapted from: CDC. General recommendations on immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP) and the American Academy of Family Physicians (AAFP). MMWR 2002; 51 (No. RR-2):7.

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